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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,943	01/25/2001	Eyal Raz	UCAL173CON	8209
25226	7590	10/06/2003	EXAMINER	
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			SCHULTZ, JAMES	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/770,943

Applicant(s)

RAZ ET AL.

Examiner

J. Douglas Schultz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5 and 10-13, drawn to a pharmaceutically useful compound for inhibiting immunostimulation by immunostimulatory sequence oligodeoxynucleotides comprising an oligonucleotide containing a hexamer region having the nucleotide sequence AAGGTT, classified in class 536, subclass 23.2.
 - II. Claims 1-4, 6, and 10-13, drawn to a pharmaceutically useful compound for inhibiting immunostimulation by immunostimulatory sequence oligodeoxynucleotides comprising an oligonucleotide containing a hexamer region having the nucleotide sequence AAGCTT, classified in class 536, subclass 23.2.
 - III. Claims 1-4, 7, and 10-13, drawn to a pharmaceutically useful compound for inhibiting immunostimulation by immunostimulatory sequence oligodeoxynucleotides comprising an oligonucleotide containing a hexamer region having the nucleotide sequence AGGGCT, classified in class 536, subclass 23.2.
 - IV. Claims 1-4, 8, and 10-13, drawn to a pharmaceutically useful compound for inhibiting immunostimulation by immunostimulatory sequence oligodeoxynucleotides comprising an oligonucleotide containing a hexamer
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region having the nucleotide sequence GAGGTT, classified in class 536, subclass 23.2.

V-XXIII. Claims 1-4, 9, and 10-13, drawn to a pharmaceutically useful compound for inhibiting immunostimulation by immunostimulatory sequence oligodeoxynucleotides comprising an oligonucleotide containing a hexamer region having the nucleotide sequence AAGCTT, AGGCTC, GAGCTT, GGGCTT, AAGCTC, AGGCTC, GAGCTC, GGGCTC, AAGCCC, AGGCCC, GAGCCC, GGGCCC, AGGCCT, GAGCCT, GGGGCT, TTGCAA, AATGTT, GGGGTT and AAGCCC, wherein each sequence comprises its own group respectively, classified in class 536, subclass 23.2.

XXIV. Claims 14-19, and 22-24, drawn to a method for inhibiting the immunostimulatory activity of ISS-ODN in contact with a population of vertebrate cells which includes lymphocytes or monocytes comprising contacting the population of vertebrate cells with an immunoinhibitory amount of an oligonucleotide, or classified in class 514, subclass 44.

XXV. Claims 20 and 21, drawn to a method for prolonging gene expression in a recombinant expression vector believed to contain at least one ISS-ODN comprising contacting the recombinant expression vector with an immunoinhibitory amount of an oligonucleotide containing a hexamer region, classified in class 514, subclass 44.

XXVI. Claim 25, drawn to a method for boosting a Th2 type immune response to an antigen comprising contacting a population of antigen stimulated vertebrate cells

including lymphocytes with an immunostimulatory amount of an oligonucleotide, classified in class 514, subclass 44.

XXVII. Claims 26-29, drawn to a method for identifying oligonucleotides which inhibit the immunostimulatory activity of immunostimulatory oligonucleotides, and the oligos that are identified by such a process, and to a method for detecting ISS-ODN activity in a host classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the hexamer sequences listed in claim 1-9 are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434)

Groups I-XXIII specifically claim numerous hexamer, which are targeted to and modulate the expression of oligo sequences containing an immunostimulatory sequence. The instant hexamer sequences are considered to be unrelated, since each hexamer sequence claimed is structurally and functionally independent and distinct for the following reasons: each hexamer sequence has a unique nucleotide sequence, each hexamer sequence targets a different and specific CpG motif, and each hexamer, upon binding to it target, is presumed to functionally modulate (increases or decreases) the expression of the CpG containing gene and to varying degree (per applicants' specification page 12, for example). Furthermore, a search of more than one (1) of the hexamer sequences as claimed presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of

more than one (1) of the claimed antisense sequences. In view of the foregoing, one (1) hexamer sequence is considered to be a reasonable number of sequences for examination. Accordingly, should applicants elect to have any of the groups containing claims 1-9 examined, applicants are required to elect the group containing the one (1) hexamer sequence of interest.

The inventions of groups I-XXIII and those of groups XXIV-XXVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of groups I-XXIII are oligomers that can be used as probes for identifying the presence of specific gene sequences in homogenates, or as primers in PCR amplification procedures, and are not solely required for use in applicants' methods of groups XXIV-XXVII.

Inventions of groups XXIV-XXVII are all unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, none of the groups have been disclosed in applicants' specification as capable of being used together, and each of the methods has different modes of operation. Group XXIV has the method step of measuring the immune response generated from the administration of an oligonucleotide to a host, which is not required of any other group. The method of group XXV requires determining the duration of expression of specific vector-expressed genes in response to the administration of the instantly claimed oligos, which is not found in any other method. The method of group XXVI has the method steps of determining the

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relative increase of a type Th2 immune response that is generated in response to administration of the instantly claimed oligos, which is unique to this method. Finally, group XXVII, drawn to a method of screening for oligos that inhibit the immunostimulatory effect of ISS-ODN's, requires generating and testing a library of potential candidates, and comparing the response, which is not required of any other steps.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for each of the Groups above is not required for the other Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355.

The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD



KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER